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HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/265,307	03/09/99	WEBB	N N0260/7031 (E

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BOSTON MA 02210

HM12/1012

EXAMINER

TRINH, B

ART UNIT	PAPER NUMBER
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1612

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DATE MAILED:

10/12/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/265,307

Applicant(s)

NIGEL et al

Examiner

TRINH

Group Art Unit

1612

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8-2-99.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 5, 7, 11, 12, 17, 21, 23, 28, 33, 48-49, 55-57, 62, 65, 69-70, 78, 82, 84, 89-90, 94, 97, 101, 103, 107-108, 110, 114 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) above is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1612

Claims 1, 5, 7, 11- 12, 17, 21, 23, 28, 33, 48-49, 55-57, 62, 65, 69-70, 75, 78, 82, 84, 89-90, 94, 97, 101, 103, 107-108, 110, 114 are pending.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 7, 11-12, 17, 21, 23, 28, 33, 48-49, 55-57, 62, 65, 60-70, 75, 78, 82, 84, 89-90, 94, 97, 101, 103, 107-108, 110, 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over .

Mayhew et al or Bradley et al in view of Agharkar et al..

Mayhew et al teaches taxane attached by fatty acid are useful anticancer agent; note compound in column 2 of the patent. Bradley et al also teaches that a specific fatty acid; i.e., docosahexaenoic acid, attached to taxol~~g~~ forming a conjugate which also is useful anticancer agent; note compounds in column 3 and 4 of the patent. Agharkar et al teaches that a composition containing taxane and the instant surfactant, i.e., polyoxyethylate castor oil; has improved the bioactivity of taxane; note lines 38-54 column 1 and lines 42- 62 column 2 of the patent. Thus it would be obvious to prepare a fatty acid conjugated with taxane to form a fatty acid-taxane conjugate as taught by Mayhew et al or Bradley et al and add a surfactant to the same to forma composition having the improved bioactivity.

Art Unit: 1612

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 7, 11-12, 17, 21, 23, 28, 33, 48-49, 55-57, 62, 65, 69-70, 75, 78, 82, 84, 89-90, 94, 97, 101, 103, 107-108, 110, and 114 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,919,815. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant taxane embraces the taxol species and the fatty acid embraces docosahexaenoic acid as a species.

No claim is allowed.

Any inquiry concerning this communication should be directed to Ba Trinh at telephone number (703) 308-4545.

Application/Control Number: 09/265,307

Page 4

Art Unit: 1612

Trinh/Fisher

October 4, 1999

A handwritten signature in black ink, appearing to read 'Ba K. Trinh', with a stylized, flowing script.

**BA K. TRINH
PRIMARY EXAMINER
GROUP 1200**